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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,143	03/26/2001	Michael G. Walker	PB-0004-1 CIP	2083

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EXAMINER	
CARLSON, KAREN C	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,143	WALKER ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears n the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *4-11 and 17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Invention 6, Claims 1-3 and 12-14 as drawn to SEQ ID NO: 6 in Paper No. 8, filed July 15, 2003 is acknowledged. The traversal is on the ground(s) that the restriction is excessive that the MPEP indicates that p to 10 nucleotide sequences can be searched. This is not found persuasive because, as noted in the restriction requirement, the nucleotide sequences differ in structure from one another, and are co-expressed with different matrix proteins, having different function. Therefore, the search of one is not a search of the other sequences. Additionally, the issues of utility and enablement varies across the nucleic acids claimed. Therefore, this argument is not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Upon search and examination of SEQ ID NO: 6, the Examiner attempted to find utility through the encoded polypeptide, SEQ ID NO: 22. Because the polypeptide has been searched and addressed below, Invention 59, Claims 15 and 16, drawn to SEQ ID NO: 22, has been rejoined with Invention 6, drawn to SEQ ID NO: 6.

Claims 1-19 are currently pending. Claims 4-11 and 17-19 are withdrawn from further examination by the Examiner because these claims are drawn to non-elected inventions. Claims 1-3 and 12-16, as drawn to SEQ ID NO: 6 or NO: 22, are under examination.

Priority is set to the filing date of SN 09/169,289, filed October 9, 1998.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 12-16 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The specification teaches that the polynucleotide of SEQ ID NO: 6, which encodes the polypeptide of SEQ ID NO: 22, is a matrix-remodeling gene because it is coexpressed with known matrix-remodeling genes. Coexpression of genes does not provide evidence regarding the function of the encoded gene product. Further, even if the gene encodes a protein involved in matrix-remodeling, its role or activity in matrix-remodeling has not been disclosed. For example, at page 1, line 11+, the specification teaches that matrix remodeling is associated with the construction, destruction, and reorganization of extracellular matrix components, and is essential in normal cellular functions and also in many disease processes including angiogenesis, arthritis, atherosclerosis, cancers, cardiomyopathy, diabetic necrosis, fibrosis, and ulceration. At page 23, the specification states that the known matrix remodeling gene products are categorized as extracellular matrix component proteins, matrix proteases and matrix protease inhibitors, and regulatory proteins that control the expression of matrix remodeling genes. Pages 23-25 list the functions of 21 known matrix remodeling gene and their gene products. Taken in total, the assertion that SEQ ID NO: 6 and its encoded protein SEQ ID NO: 22 are involved in matrix remodeling because the gene is coexpressed with known matrix remodeling genes lacks basis for utility because coexpression of a gene does not correspond to gene or gene product function. The assertion that SEQ ID NO: 6 and its encoded protein SEQ ID NO: 22 is a matrix remodeling gene and gene product lacks basis for utility because the biological function of the gene product has not been taught.

Other utilities set forth in the specification for SEQ ID NO: 6 and its encoded protein SEQ ID NO: 22 include the diagnosis, prognosis, prevention, treatment, and evaluation of therapies for diseases associated with matrix remodeling such as cancer (including adenocarcinoma, leukemia, lymphoma, melanoma, myeloma, sarcoma, teratocarcinoma, and cancers of the adrenal gland, bladder, bone, bone marrow, brain, breast, cervix, gall bladder, ganglia, GI tract, heart, kidney, liver, lung, muscle, ovary, pancreas, parathyroid, penis, prostate, salivary

glands, skin, spleen, testis, thymus, thyroid, uterus as set forth at page 15, line 21+), cardiomyopathy, arthritis, angiogenesis, diabetic necrosis, atherosclerosis, fibrosis, and ulceration (page 1, para. 2). As noted above, coexpression of genes says nothing about gene or gene product function. Additionally, the gene and gene product function has not been elucidated. Further, there is no showing that SEQ ID NO: 6 or its encoded protein SEQ ID NO: 22 is expressed in these tissues, these tissues greater than other tissues, or in cancerous versus non-cancerous tissue, for example.

The polynucleotide sequence consisting of SEQ ID NO: 6 may have utility because it encodes a protein having utility. At page 29, para. 1, SEQ ID NO: 22 is stated to be a 99 amino acid sequence that resembles RH1 and RH2 opsins, that are a family of G-protein coupled receptors that mediate vision. Review of the art surrounding opsins shows that opsins are G-protein coupled receptor comprising approximately 350-400 amino acids, said receptor having seven transmembrane domains. See, for example, Cowman et al. (1986; Cell 44: 705-710), Kaushal et al. (1994; PNAS 91: 4024-4028), Pasqualetti et al. (2003; Eur. J. Neurosci. 18 : 364-372), and Zuker et al. (1985; Cell 40: 851-858). Thus, SEQ ID NO: 22 is not an opsin receptor, and SEQ ID NO: 6 does not encode an opsin receptor.

The asserted utilities are general utilities and do not form a substantial utility because further research is needed to identify or reasonably confirm a real world context of use for SEQ ID NO: 6 and its encoded protein SEQ ID NO: 22. Therefore, because Applicant has not disclosed any specific or substantial utility for the claimed invention, credibility will not be assessed.

Claims 1-3 and 12-16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims comprise subject matter drawn to non-elected inventions. Therefore, these claims do not particularly point out and distinctly claim the subject matter of the elected invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Karen Cochrane Carlson PhD

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER